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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,829	06/26/2003	Ewa Herbst	286932.125US2	7587
28089	7590	07/02/2007		
WILMER CUTLER PICKERING HALE AND DORR LLP 399 PARK AVENUE NEW YORK, NY 10022			EXAMINER MULLEN, KRISTEN DROESCH	
			ART UNIT	PAPER NUMBER
			3766	
			NOTIFICATION DATE	DELIVERY MODE
			07/02/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/608,829	Applicant(s) HERBST ET AL.	
	Examiner Kristen Droesch Mullen	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10-19 and 21-36 is/are rejected.
- 7) ☒ Claim(s) 7, 9 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/26/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/21/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be *material to patentability* as defined in 37 CFR 1.56.

A **correct** statement in compliance with 37 CFR 1.56 should read: "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

Examples of **incorrect** statements are:

- "I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)"
- "I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)"
- "I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)"

Specification

2. The disclosure is objected to because of the following informalities: The Claims do not commence on a separate sheet. See 37 CFR 1.75(h) and MPEP § 608.01(m).

Appropriate correction is required.

3. The specification contains a reference to the parent application by its application number. This application has since been issued. The examiner respectfully requests that the parent

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application information be updated in the specification along with any other referenced application numbers in the specification that have matured into patents.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Nordenstrom et al. (4,289,135).

Regarding claims 1 and 35, Nordenstrom shows at least two electrodes (9, 12) adapted to be attached to the tissue and means to apply a voltage across the electrodes to cause a current to flow through the tissue which brings about an electrochemical reaction yielding said cytotoxic agent (chlorine) (Col. 2, lines 24-65).

6. Claims 10-16, 18, 29-30 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Berg et al. (2005/0177207).

With respect to claim 10, Berg shows a working electrode and a counterelectrode, each electrode adapted to be positioned in said patient within or near said tissue means for applying a voltage effective to induce a current between the electrodes and means for regulating the voltage across the electrodes (para. 0029); a precursor of a compound having cytotoxic activity against

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the tissue; and means for introducing said precursor into said patient into or near said tissue, said precursor being activated by illumination from a light source (paras. 0030-0034).

Regarding claim 11, Berg also shows at least one of said electrodes is adapted to receive a fiber optic (needle electrode) (paras. 0053).

With respect to claim 12, Berg also shows one of the electrodes is hollow and porous (needle electrode) (paras. 0053).

Regarding claims 13-14, the examiner considers the recitations to be statements of intended use, which do not impart any structure that is distinguishable over the prior art. For example, the claim recitations do not describe a controller that is programmed to perform said functions nor utilize means-plus-function language.

Regarding claims 15, 16 and 18, Berg shows providing an in vivo current (of photons and electrons) passing through or near said tissue; providing in or near said tissue a precursor of a compound having cytotoxic activity against said tissue; and activating said precursor to be cytotoxic (paras. 0029-0034). Berg also shows the precursor is activated by the current (of photons) and the activated by light

With respect to claims 29-30 and 36, Berg shows the patient is human or non human and the tissue is tumorous (paras. 0029, 0043).

7. Claims 15-16, 18, 29 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by McCaughan, Jr. (4,660,925).

Regarding claims 15, 16 and 18, McCaughan shows providing an in vivo current (of photons) passing through or near said tissue; providing in or near said tissue a precursor of a compound having cytotoxic activity against said tissue; and activating said precursor to be

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cytotoxic (Col. 1, lines 49-Col. 2, line 9). McCaughan also shows the precursor is activated by the current (of photons) and the activated by light

With respect to claims 29 and 36, McCaughan shows the patient is human and the tissue is tumorous (Col. 1, line 12-Col. 2, line 9).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over McCaughan, Jr. (4,660,925) as applied to claim 15 above. McCaughan is as explained before. Although McCaughan fails to teach that the patient is non-human. However, it is well known in veterinary science to treat domestic animals such as dogs and cats with chemotherapeutic agents to fight cancer. It is also well known to utilize animals for experimenting and testing new chemotherapy treatments. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of McCaughan to include non-human patients since it is well known in veterinary science to treat domestic animals with chemotherapeutic agents drugs and is also well known to utilize animals for experimenting and testing new chemotherapy treatments.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-6, 8, 10-19 and 21-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8, 10-19 and 21-36 of U.S. Patent No. 6,708,066.

For double patenting to exist as between the rejected claims and the patent claims, it must be determined that the rejected claim is not patentably distinct from claims 1-6, 8, 10-19 and 21-36. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and claims xxx and, if so, whether those differences render the claims patentably distinct.

The difference between claims 1-6, 8, 10-19 and 21-36 of the application and claims 1-6, 8, 10-19 and 21-36 of the patent lies in the fact that the patent claim includes many more elements and is thus much more specific.

It is clear that all the elements of claims 1-6, 8, 10-19 and 21-36 are to be found in claims 1-6, 8, 10-19 and 21-36. Thus, the invention of claims 1-6, 8, 10-19 and 21-36 of the patent is in effect a "species" of the "generic" invention of claims 1-6, 8, 10-19 and 21-36 of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1-6, 8, 10-19 and 21-36 are anticipated by claims 1-6, 8, 10-19 and 21-36 of the patent, they are not patentably distinct from claims 1-6, 8, 10-19 and 21-36.

Allowable Subject Matter

12. Claims 2-6, 17, 19-28, and 31-34 would be allowable if rewritten to overcome the Double Patenting rejection(s) set forth in this Office action and to include all of the limitations of the base claim and any intervening claims or upon the filing of a Terminal Disclaimer.

13. Claim 7, 9 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Droesch Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

kdm

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